Submitter : Dr. Gail Whitelaw **Date:** 09/16/2005

Organization : American Academy of Audiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-600-Attach-1.PDF

#600

AMERICAN ACADEMY OF AUDIOLOGY

11730 Plaza America Drive, Suite 300, Reston, VA 20190-4798 • 1-800-AAA-2336

September 16, 2005

BY ELECTRONIC MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: CMS-1501-P – Comments regarding Device-Dependent APCs and APC Groups

The American Academy of Audiology appreciates this opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to amend the Medicare Hospital Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2006. 70 Fed. Reg. 42674 (July 25, 2005).

The Academy, representing 9,700 audiologists nationwide, is concerned by the proposed cut in payment for cochlear implant surgery. We appreciate CMS' willingness in the past to work with providers to improve OPPS payment for cochlear implantation, and we hope that CMS will be able to avoid this proposed reduction. In addition, we would like to request further guidance relating to the rationale for the change in APC of several audiology procedures.

DEVICE-DEPENDENT APCs

The proposed rule would decrease the payment for cochlear implantation from $25,307 in 2005 to $21,739 in 2006. Such a large reduction will have repercussions on access to cochlear implant services. More hospitals are likely to close their cochlear implant centers, and those that remain may be under pressure to reduce their volume of surgeries. Payment reductions and year-to-year fluctuations in payment rates also discourage hospitals from opening new CI centers and discourage surgeons and audiologists from entering this sub-specialty.[1]

The Lewin Group was commissioned to review external data on cochlear implant invoice prices to derive a bona fide payment rate for APC 0259. Using confidential pricing information

[1] In the preamble to the proposed rule, CMS acknowledges that "a payment reduction of more than 15 percent from the CY 2005 OPPS to the CY 2006 OPPS may be problematic for hospitals that provide the services contained in these APCs." 70 Fed. Reg. at 42714. Yet, CMS has proposed a reduction nearly as large, 14 percent, for cochlear implantation.

supplied by three cochlear implant manufacturers, Lewin calculated a weighted average industry invoice price of $21,827 for a cochlear device, far above the median device cost of $16,408 that CMS determined using 2004 claims data. Using this more representative device cost, The Lewin Group calculated a payment rate for APC 0259 of $27,192. The Academy urges CMS to recalibrate the relative weight of APC 0259 using the external device cost data collected by The Lewin Group.

If CMS does not recalibrate according to this supplemental data, at the very least, the Academy requests that CMS continue the 2005 payment rate for APC 0259, adjusted for inflation, in 2006. In the long run, we hope that CMS will seriously consider modifying the methodology it uses to set relative weights for device-dependent APCs so that cochlear implantation can be adequately reimbursed.

Ready access is required for cochlear implantation to be effective in seniors. Follow-up care, mapping the device's electronics and maintaining a well-tuned, functional device is critical to ensuring optimal results. If reimbursement cutbacks were to reduce access to services, seniors would be forced to travel longer distances for after-surgery care and less likely to be achieving optimal outcomes. Cochlear implant services improve the quality of life. Cochlear implantation increases the independence of Medicare beneficiaries and the ability of a senior to remain self-sufficient.

APC GROUPS

In the proposed rule, CMS proposes to change the Ambulatory Payment Classification (APC) for four audiology procedures. CMS proposes to make the following transfers: CPT codes 92553 (audiometry, air & bone) and 92572 (staggered spondaic word test) from APC 0364 to APC 0365; CPT code 92561 (Bekesy audiometry, diagnosis) from APC 0365 to APC 0364; and CPT code 92577 (Stenger test, speech) from APC 0365 to APC 0366. CMS does not provide any explanation for these proposed changes in the preamble to the proposed rule.

While the Academy does not object to these changes, we request that CMS provide an explanation so that we can understand the rationale for the changes. CPT code 92553 is a common service provided by audiologists and we would like to have a better understanding regarding the motivation for this change.

The Academy appreciates CMS' consideration of these comments.

Respectfully submitted,

Gail M. Whitelaw

Gail Whitelaw, Ph.D.
President

Submitter : Mr. David McClure **Date:** 09/16/2005

Organization : Tennessee Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-604-Attach-1.DOC

September 16, 2005

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-1850

Ref: CMS-1501-P — Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Rates

Dear Sirs:

On behalf of the Tennessee Hospital Association (THA), we appreciate the opportunity to submit comments on the calendar year (CY) 2006 outpatient prospective payment system (OPPS) proposed rule.

THA, established in 1938, serves as an advocate for hospitals, health systems and other healthcare organizations and the patients they serve. The association represents over 200 healthcare facilities, including hospitals, home care agencies, nursing homes, and health-related agencies and businesses, and over 2,000 employees of member healthcare institutions, such as administrators, board members, nurses and many other health professionals. THA is the premiere organization in Tennessee that promotes and represents the interests of all health careers, hospitals and health systems.

The following are THA's detailed comments regarding CMS' proposed changes.

EXPIRING HOLD HARMLESS PROVISION FOR TRANSITIONAL CORRIDOR PAYMENTS FOR CERTAIN RURAL HOSPITALS

The THA is concerned about the impact that the expiration of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. THA recommends the provision be expanded to permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

INPATIENT PROCEDURES

CMS proposes to remove 25 codes from the "inpatient only" list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The THA continues to urge CMS to eliminate the "inpatient only" list. Physicians, not hospitals, determine where procedures can be performed safely, as well as whether a patient's condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, then under current rules the hospital is penalized if that procedure happens to be on the "inpatient only" list.

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospitals' losses when treating high-cost cases. For 2006, CMS proposes reducing the outlier pool to 1 percent of total outpatient PPS payments. Further, CMS says that the fixed-dollar threshold should be increased by $400, to $1,575, to ensure that estimated 2006 outlier payments would equal 1 percent of total outpatient PPS payments. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,575 more than the APC rate.

While the THA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, we are concerned that CMS has set the thresholds for outliers in this rule too high. The THA seeks further clarification from CMS regarding how the agency determined that a $400 increase in the fixed-dollar threshold was appropriate and how the $1,575 fixed-dollar threshold was calculated.

THA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact me at 615-256-8240.

Sincerely,

David McClure
THA Vice President of Finance
500 Interstate Blvd South
Nashville, TN 37210

Submitter : Darla Perry **Date:** 09/16/2005

Organization : LAAH

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

Please review attached.

CMS-1501-P-602-Attach-1.DOC

CMS-1501-P-602-Attach-2.DOC

CMS-1501-P-602-Attach-3.DOC

Attachment #602

PERRY & CO. CPA's

514 W. NAPOLEON ST. SULPHUR, LA 70663

(337)528-4000 (Telephone) (337)528-4010 (FAX)

Date: September 16, 2005

FILE CODE: CMS-1501-P PARTIAL HOSPITALIZATION
Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates – Proposed Rule

I serve as an outside Certified Public Accountant to over 25 freestanding Community Mental Health Centers based in Louisiana, Mississippi and Texas. This is my second comment to rule. I have performed a cost calculation for 18 providers in Louisiana that are not major MSA areas – (New Orleans and Baton Rouge). The average mean cost per day came to $263.12 which is significantly higher than the amount listed in the proposed rule. Perhaps the larger agencies in the major MSA areas are skewing the cost data or perhaps the number of days is miscalculated.

The proposed rule referenced above effectively decreases the net daily partial hospitalization reimbursement rate for freestanding providers to approximately $169. per day. This $169. is significantly lower than the cost I have calculated for these 18 providers. The population served by these providers are largely below poverty level and do not have secondary or private insurance nor funds to pay the difference. Also, Louisiana Medicaid does not cover this service. Therefore when a rate of $241.57 is set and the net payment ends up approximately $165. per day for these providers – agencies cannot remain open.

I have attached my survey cost spreadsheet for review. Perhaps the CMHC data costs listed in the rule are skewed due to the larger agencies in larger MSA areas. These rural providers in Louisiana actually receive less instead of an add-on like other programs for offering services to rural beneficiaries.

CMS noted in the final rule that they would accumulate appropriate data and determine if refinements to the per diem methodology was warranted. The current proposed rule acknowledges that appropriate cost data from CMHC's has not been utilized due to aberrant data. The proposed cut of approximately 15% is not reflective of the cost pattern for the freestanding CMHC partial programs that I represent. The inflation rate alone for the medical industry is approximately 3.5%.

Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

CMHC'S are requesting that a fair rate be paid for an intensive day of outpatient PHP services. A payment decrease of 15% for APC Code 033 is definitely too drastic for the intense services delivered based upon CMS cost analysis data of the components involved. In recognition by CMS that medical costs have increased an average of 3.5%, I am requesting that the current payment rate for partial hospitalization programs not be cut. In light of the recent tragedy in our state caused by Hurricane Katrina, the services for these patients will be extremely important. We are asking to leave the 2005 rate in place for 2006 to avoid interruption of services for these patients.

I appreciate your consideration of my comments.

Darla B. Perry, CPA

ATTACHMENT: CMS MEDIAN COST DATA PER hcpcs_medians-1501p.xls CMS1501-P

BREAKDOWN OF CMS PUBLISHED COSTS FOR OUTPATIENT PSYCHIATRIC SERVICES

The following information is from the CMS 1501-P calculated median costs for services.

This information is based on CMS gathered data for the HCPCS codes, provided within an outpatient hospital setting. Please take into account that the cost for providing these outpatient services is generally less than that in a partial hospital program, due to the additional components which are expected to be included within a day of partial hospitalization, as well as the additional acuity of the patients being treated.

CMS has clearly defined what must be included in a day of partial hospitalization. The Local Medical Review Policy calls for a minimum of 4 hours per day, five days per week. The minimum which will pass through the OCE is 3 separate therapies per day, a minimum of four out of every seven days. It has clearly been defined and expected that providers will exceed this minimum level.

The average provider of Partial Hospital Services within Louisiana provides 4 therapies per day, five days per week. CMS has also specified that each therapy must be a minimum of 45 minutes. The following is a chart which provides data on the costs of the HCPCS codes which are included within APC 33.

CPT	Description	True Median Cost
90853	Group Therapy	82.31
90847	Family Psychotherapy w/patient present	140.10
90818	Individual Psychotherapy in a Partial Hospital Setting 45-50 minutes	99.63

Based on the figures above, an average day of services median cost for 4 group sessions would be $329.24 For a day with mixed sessions it would be $404.35 median cost (2 group sessions, one individual session, one family therapy session) How can a rate of $241.57 be appropriate for APC 033?

Under the proposed rule Louisiana providers will be receiving $169.00 per day (due to wage index and copay). Clearly this rate is inadequate. We are only requesting that providers be paid a rate which at a minimum covers the cost of providing services.

Please consider the above information for inclusion in comment to the proposed rule 1501-P.

#602-#3
#3

PARTIAL/CMHC PATIENT COSTS PER DAY

PROVIDER KEY # BLIND		CO INS. W/S D, LINE 9 (BOTH COLUMNS)	MEDICARE # OF DAYS	W/S A LINE 65, COL 3	W/S C TOTAL COSTS LINE 39.01, COL 1	W/S C MCARE COSTS LINE 39.01, COL 3	W/S C AVG COST PER DAY MEDICARE	AVG COST MEALS TRANSPORT PER DAY	TOTAL AVG COST PER DAY
		94,995	1953	$779,800	$721,984	$663,864	$339.99		
		136,405	2804	$591,661	$732,570	$725,571	$258.78		
		366,026	7524	$1,709,960	$1,551,742	$1,537,319	$204.33		
		152,006	3124	$639,079	$599,368	$596,821	$191.01		
		138,208	2841	$749,313	$825,557	$824,708	$290.30		
		357,702	7353	$1,166,541	$1,436,650	$1,415,454	$192.51		
		125,475	2579	$389,232	$419,730	$416,315	$161.42		
		424,383	8723	$1,009,357	$994,337	$994,337	$113.99		
		367,093	7546	$1,885,873	$1,293,397	$1,186,398	$157.23		
		293,120	6025	$999,379	$768,842	$671,990	$111.53		
		177,629	3651	$616,433	$813,688	$780,678	$213.82		
		995,621	20465	$3,784,978	$3,251,933	$3,145,713	$153.71		
		400,198	8226	$1,263,274	$1,155,784	$1,155,784	$140.50		
		190,460	3915	$1,006,157	$923,619	$893,439	$228.21		
		18,648	383	$181,732	$422,147	$399,328	$1,041.79		
		700,669	14402	$3,907,570	$2,110,606	$2,017,535	$140.08		
		95,674	1967	$518,404	$497,339	$497,339	$252.90		
		79,534	1635	$578,908	$567,481	$536,222	$328.00		
TOTAL		**5,113,846**	**105,115**	**$21,777,651**	**$19,086,774**	**$18,458,815**	**$251.12**	**$12.00**	**$263.12**

MEAN AVG

Submitter : **Ms. Barbara Mocnik** **Date: 09/16/2005**

Organization : **El Camino Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-603-Attach-1.DOC

September 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

El Camino Hospital is a hospital and psychiatric provider in California. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1501-P and a 14% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of $241.57 cannot be justified with these expenses.

2. CMS identified the Median cost of group therapy at $82.31. Our program offers up to 4 services per day. This summarizes to a median cost of $329.24. A per diem of $241.57 cannot be justified with these expenses.

3. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

4. Based on the above issues, El Camino Hospital asks that CMS leave the per diem unchanged from the CY 2005 rate of $281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP/OP programs have an average daily census of 30 patients so far in CY 2005, and every one would be a high-risk candidate for decompensation without the PHP/OP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Barbara A. Mocnik, RN, CNS
Program Manager
El Camino Hospital Outpatient Psychiatric Services
(650) 940 7187

Submitter : **Dr. Nathan Every** **Date: 09/16/2005**

Organization : **Frazier Healthcare Ventures**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-605-Attach-1.DOC

available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code. This often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries and many commercial payers thus denying Medicare patients access to technology. The end result of the proposed rule would be a disincentive for manufacturers, particularly smaller ones, to innovate and market novel and beneficial medical technologies.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives from manufacturers on the decision making panel and offer additional concerned parties the opportunity to participate, comment, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiaries full access to the same high quality care in the hospital outpatient setting realized by patients covered by private insurance. The present new technology payment system allows innovation to reach patients quickly after FDA approval and consultation with physicians. The system can reduce the delay in new technologies reaching patients by up to two years.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely,

Nathan R. Every
General Partner
Phone: 206-621-7200
601 Union Street, Suite 3200
Seattle, WA 98101
nathan@frazierhealthcare.com

Submitter : Wendy Wifler **Date:** 09/16/2005

Organization : Accuray Incorporated

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Microsoft Word attachment re: CMS-1501-P Stereotactic Radiosurgery (SRS). File named 'Accuray HOPPS Final 9.16.05.doc'.

CMS-1501-P-606-Attach-1.DOC

CMS-1501-P-606-Attach-2.DOC Duplicate ?

ACCURAY™

Attach. # 1

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, CA 94089

T: 408.716.4600
F: 408.716.4601
www.accuray.com

Attachment #606

September 16, 2005

Reference file code: CMS-1501-P
Specific issue "Stereotactic Radiosurgery (SRS)"

Image-Guided Stereotactic Robotic Radiosurgery

Accuray, manufacturer of the image-guided stereotactic robotic radiosurgery system with the brand name "CyberKnife®", respectfully submits the following comments on stereotactic radiosurgery (SRS), SRS HCPCS codes and their associated APC groups.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of SRS and maintain a process that allows for tracking of new technology claims.

We would like to take this opportunity to further assist CMS in its efforts to establish accurate codes for new technologies and clarify for others some definitions related to robotic radiosurgery. Broadly categorizing systems based on radiation source type (currently cobalt and linac) does fully recognize material differences in resources utilized due to different capabilities or process of care.

> ***Clinical application.*** Image-guided stereotactic robotic radiosurgery is both an alternative to surgery and an adjunct to radiotherapy, involving a defined set of clinical resources to deliver effective treatment. Both clinicians and patients have recognized the benefits of radiosurgery, which include no incisions, no anesthesia, lower risk of complications, and, therefore, improved patient quality of life. The CyberKnife robotic radiosurgery system enabled clinicians to offer certain clinical benefits, as proven in the practice of intracranial radiosurgery, to patients with lesions and tumors in other parts of the body and in lesions that move with respiration.
>
> For intracranial lesions: The combination of non-invasive real-time image-guided radiosurgical accuracy with the ability to fractionate is an important CyberKnife capability. The CyberKnife eliminates the need for the head frame attached to the patient's skull and allows physicians to fractionate radiosurgery procedures over several days and increase the types of lesions that may successfully be treated.
>
> For radiosurgical targets outside the head, all of which have a potential for motion during the treatment cycle, regardless of the care and extensiveness of immobilization applied: The CyberKnife combination of the ability to deliver radiation from a virtually infinite array of angles and positions (non-isocentric "dose painting"), radiological targeting capability, real-time target tracking capability and radiosurgical accuracy is, to date, unique. Only the CyberKnife uses the Synchrony™ System, which permits tracking of respiration-induced movement.

ACCURAY™

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Robotic radiosurgery. There are those in the radiation community who have asserted publicly that there is confusion about the definition of "robotic." Because the CyberKnife is genuinely robotic, we believe that we can clear up any such confusion. The CyberKnife delivers image-guided stereotactic robotic radiosurgery by positioning for beam delivery with the use of a robotic manipulator and image guidance system that directs the linear accelerator, which administers the radiation. The CyberKnife is an autonomous robot. An autonomous robot is a device that automatically performs complicated, often repetitive, tasks, guided by, automatic controls; gaining information about the environment; traveling from point A to Point B, without human navigation assistance; avoiding situations that are harmful to people, property, or itself; adjusting strategies based on the surroundings; and adapting to its surroundings without outside assistance. Older systems now claiming to be robotic are not robotic but rather remotely driven mechanical systems. The other systems could eventually get closer to being fully robotic but their current designs cannot be adapted to adjust strategies based on the surroundings or to adapt to surroundings without outside assistance. These two functions are what make CyberKnife different than all other current systems. While treating moving or stationary targets, CyberKnife continually adjusts and adapts without outside assistance. The image guidance system acts as the eyes of the system, the computer hardware and proprietary software are the brain and the linac is equivalent to the surgeon's tool - all of these elements continually work together to deliver the treatment.

Conformal, non-isocentric beam delivery. The use of robotics and image-guidance allows the automatic delivery of non-coplanar, non-isocentric beams to any part of the body, minimizing entrance and exit beam interactions so as to decrease dose accumulation. No patient or manual beam repositioning is needed to achieve non-coplanar beam delivery. CyberKnife was inherently designed with capability to deliver non-isocentric, non-coplanar beams to maximize conformality, with no movement of the patient and no reconfiguring of the machine, except for collimator changes which are prescribed at the clinician's discretion.

Real-time image-guidance with continuous target tracking and feedback. This is the virtually instantaneous and continuous feedback loop between X-ray-based target localization and automatic correction of accelerator therapeutic radiation delivery throughout the entire treatment. The CyberKnife can dynamically target the tumor and adjust the beam to follow the motion of the lesion throughout the treatment, directing the beam to precisely match target lesion movement, enabling frameless radiosurgical treatment, and allowing radiosurgical accuracy to be extended to target lesions throughout the body, even though they are more prone to movement over the time of the treatment compared with intracranial lesions. Continuous target lesion tracking and dynamic treatment correction also differentiate CyberKnife image-guided stereotactic robotic radiosurgery from intensity modulated radiation therapy (IMRT), by allowing subtraction of target lesion motion uncertainty in the design of the planning target volume (PTV), translating to the ability to more accurately encompass an entire target lesion with a much smaller margin, creating superior sparing of adjacent tissue, allowing the use of radiosurgical dose fractionation. The CyberKnife system employs a proprietary method of target tracking that updates the target lesion location and automatically positions the radiation beam with sub-millimeter accuracy[1] throughout the entire treatment. The real-time image-guided robotics allows the CyberKnife to continuously monitor and correct for patient movements throughout treatment.

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Respiratory tracking. This represents a secondary target tracking mechanism, called Synchrony that may be added to the primary tracking method described above, specifically for targeting lesions that move with respiration. Virtually all CyberKnife providers offer both tracking mechanisms. Synchrony software and hardware correlate externally detected respiratory body motion with internal target lesion motion, allowing the stereotactic robotic radiosurgery system to move the linear accelerator continuously, to track the target lesion as it moves throughout the respiratory cycle, with a total clinical accuracy of less than 1.5 mm [2]. Real-time respiratory target lesion tracking capability further distinguishes the CyberKnife system from older modalities. No other technology available today offers this capability.

1. C Yu, W Main, D Taylor, G Kuduvalli, MLJ Apuzzo, JR Adler Jr, MY Wang. An anthropomorphic phantom study of the accuracy of CyberKnife spinal radiosurgery. Neurosurgery 55(5): 1138-1149, Nov 2004.
2. S Dieterich, D Taylor, C Chuang, K Wong, J Tang, W Kilby, W Main. The CyberKnife Synchrony Respiratory Tracking System: Evaluation of systematic targeting uncertainty. White paper presented at ASTRO 2004.

In summary, because of the attributes described above, the CyberKnife is a complex image-guided stereotactic robotic radiosurgery system, delivering radiosurgical precision throughout the body, for the number of treatments (fractions, maximum five) as the clinician deems necessary for a given situation.

SRS Codes

In 2003, CMS established new HCPCS codes for image-guided stereotactic robotic radiosurgery to distinguish these services from other linac-based stereotactic radiotherapy systems that are substantially less resource-intensive. We will offer recommendations on each.

CMS established HCPCS G0339, which describes image-guided robotic linac stereotactic radiosurgery completed in one treatment session (or the first of multiple treatment sessions), and assigned this new code to New Technology APC 1528. CMS also established HCPCS G0340, which describes the second and any subsequent treatment sessions of stereotactic radiosurgery (up to five treatment sessions), and assigned this new code to New Technology APC 1525, with a rate that is approximately 70% of the rate for the first treatment.

In light of recent historical treatment of SRS codes, we now encourage CMS to refrain from treating different forms of SRS (i.e. cobalt vs. linear accelerator-based) differently by "bundling" treatment planning and treatment for cobalt-based systems and "unbundling" these services for linear accelerator-based systems. The clinical processes of treatment planning and treatment administration are distinct, and distinct and varying resources are used for each. These services are included in separate subsections of the CPT and coding conventions for each are well established. We believe that "bundling" treatment planning and treatment administration for one SRS modality while "unbundling" it for another is potentially confusing and counterproductive.

ACCURAY

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Recommendations:

1. We agree with the recommendation of CMS staff to eliminate planning code G0338 and use existing CPT codes for treatment planning, which will more accurately reflect the actual planning process.

2. Accuray supports the *CyberKnife Coalition's* recommendations that CMS:

   A. Make G0339 image-guided robotic stereotactic radiosurgery a permanent code at the current APC 1528 rate for all treatments (with maximum payment of five treatments).

   B. Eliminate G0340 at APC 1525 and use G0339 at the current APC 1528 payment rate for all treatments.

We appreciate your consideration of our comments.

Sincerely,

Wendy E. Wifler
Senior Director, Health Policy & Payment
Accuray Incorporated

Cc: Euan Thomson, CEO Accuray Incorporated

Submitter : Mr. Paul Quinn

Date: 09/16/2005

Organization : Saint Anne's Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-607-Attach-1.DOC

Attachment #607

September 16, 2005

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-1501-P: Proposed Changes to the Hospital Outpatient PPS

Dear Dr. McClellan,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the "Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" as published in the July 25, 2005, *Federal Register*.

We are specifically providing comments on proposed partial hospitalization program (PHP) and community mental health issues.

About NAPHS
Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 400 specialty hospitals, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, behavioral group practices, and other providers of care. Our members deliver all levels of care, including partial hospitalization services, outpatient services, residential treatment, and inpatient care.

Partial hospitalization – specifically – has long been a level of care offered by NAPHS members. In our most recent *NAPHS Annual Survey*, more than half of all NAPHS members responding offered partial hospitalization services for their communities. Throughout the years, these NAPHS members have been a stable group of providers working hard to meet a community need. Patients may use partial hospitalization either as a transition from a hospital program or as an alternative to inpatient care.

Providers have serious concerns with proposed partial hospitalization changes.
We are concerned that proposed changes to the outpatient prospective payment system (PPS) could negatively affect the partial hospitalization benefit. Although providers are committed to finding ways to ensure that their patients have access to this essential level of care, partial hospital capacity in the behavioral healthcare system remains a concern. Many partial programs have closed or limited the number of patients they can accept, and fewer partial hospital slots now exist nationwide.

ISSUES OF CONCERN

The current methodology for determining the PHP rate is in flux.
We appreciate the various approaches CMS considered in the 2006 proposed rule in dealing with the complexities of the historical cost data supplied by hospital and community mental health center (CMHC) providers of the partial hospitalization benefit. We agree that the range of data provided by the CMHCs throughout the last five years (with a median per diem cost ranging from a high of $1,037 to a low of $143) has made it difficult to determine actual costs. We are aware of the various strategies CMS has applied in dealing with the CMHC data, including adjusting cost-to-charge ratios, examining the influence of outlier payments, and recognizing the significant drop in the cost per day.

Based on the clinical intensity of the PHP benefit, we do not understand how it could possibly be provided for $143. This figure raises serious questions about the accuracy of the data reported on CMHC cost reports. By regulation, PHPs are required to provide a program of active treatment which includes at least three individualized treatment sessions per day, in addition to appropriate individual therapy and treatment planning. This level of intensity closely mirrors the care provided in an inpatient treatment setting. Were it not for the existence of partial hospitalization, beneficiaries would be hospitalized.

We noted the various ways CMS proposed to deal with the complexities of determining an updated payment rate (such as following the methodology used for the CY 2005 OPPS update, basing the update on hospital-based PHP data alone, or applying different trimming methodologies to CMHC cost data in an effort to eliminate aberrant data and decrease the instability in CMHC data).

We noted the desire of CMS to lessen the PHP payment reduction for CY 2006, so that you can ensure an adequate payment amount and continuing access to the partial hospitalization benefit for Medicare beneficiaries. CMS proposed a reduction of 15% as a way of doing this. The rationale for this reduction (from $289 to $245.65) states that CMS think this will recognize the decrease in the median per diem costs in both the hospital and CMHC data and also reduce the risk of any adverse impact on access to these services that might result from a large single-year rate reduction. CMS further state that you will continue to work with CMHCs to improve their reporting so that payments can be calculated based on better empirical data.

We believe that a 15% decrease in the per diem rate may negatively impact the availability of partial hospitalization to beneficiaries and is an unacceptable variance in the payment rate.
The basis of a prospective payment system is to provide stability and predictability in payment in order to encourage efficiency in the delivery of services and to allow providers to budget and plan for the provision of services. A PPS system is not designed to endure significant adjustments every year based on historical costs. Changes of the magnitude of 15% undermine the basis of the system. Providers and payers alike need to be able to rely on a predictable methodology for determining payment that will allow the PHP benefit to be available to Medicare beneficiaries in a stable way. This methodology needs to be predicated on reliable data.

We respect the thought that has gone into the determination of the proposed reimbursement rate for PHP for 2006, yet we think the methodology does not adequately account for all important variables.
Selecting the15% reduction may protect providers from more onerous cuts, but it is in itself not an acceptable solution. The volatility in the CMHC data continues to be inadequately explained.

There are many administrative costs (transportation, food) that are not Medicare-reimbursable. But they are real costs to the provider and need to be considered as payers and providers analyze the fiscal realities of providing the benefit. There are also highly prescriptive administrative and regulatory responsibilities that providers must meet in order to offer the benefit. These, too, contribute significantly to costs. Especially in the new era of Medicare inpatient psychiatric prospective payment, it is very important there be a strong alternative to hospitalization. Partial hospitalization *is* that alternative.

RECOMMENDATIONS

1. To allow the time and resources necessary to fully develop an adequate payment methodology, we propose that the 2006 PHP payment rate remain the same as the 2005 rate--$281.33. We would continue to work with CMS and others to study the data and refine the methodology to develop a payment rate that is fair and predictable.

2. Strategies that may be considered in the development of PHP rates could include the following:

- Use inpatient costs per day as the basis for the PHP median cost per diem. CMS could apply to the IPF PPS cost per diem a scaling factor (perhaps 50%) to develop a basis for the PHP median cost per diem. CMS would, in effect, develop a corollary factor between the PHP cost and inpatient psychiatric cost.

- Develop a cost method that uses, as an example, a three-year rolling average of the CMHC PHP cost per diem. This would use an average cost over time rather than a cost that has changed dramatically from year to year.

3. The successful use of any revised methodology would be dependent on developing a method for improving future CMHC cost report information. We recommend that CMS review and revise the various forms and worksheets used by CMHCs to report data. Specifically, CMS should:

a. Revise the CMHC cost report form (CMS-2088) to include a field which allows the CMHC to report its Medicare PHP days. The existing worksheet S-7, Part IV (Statistical Data) could be modified to include this new field. This field would be similar to the CMS- 2552-96 worksheet S-2, Part I field in which outpatient "Observation Bed Days" are reported. This information would then be subject to Medicare fiscal intermediary review and validation as part of the cost report desk review and audit process.

b. Revise settlement worksheet D on the CMS-2088 to include new fields that 1) display the Medicare PHP cost per day and 2) separate PHP reimbursement between outlier and non-outlier reimbursement (since the current cost report form commingles both types of reimbursement). This data will provide CMS and the provider with a quick snapshot of the facility's cost and payment per diem data. This new information will help in the Medicare fiscal intermediary's evaluation of the cost report data if any of the cost or payment PHP per diem amounts appear to be aberrant.

c. Revise the CMHC Provider Statistical & Reimbursement Report ("PS&R") Report Type: 76P to include a field which reports actual paid Medicare PHP days. This information can then be used by the provider and fiscal intermediary for the CMHC cost report submission and final settlement.

CONCLUSION

Thank you for your consideration of our comments. We look forward to continuing to work with CMS and HHS to ensure that partial hospital services remain available for the beneficiaries who require this level of care.

Sincerely,

Paul V. Quinn
Vice President
Saint Anne's Hospital
Fall River, MA 02721

Submitter : Ms. John Manter **Date:** 09/16/2005

Organization : Ms. John Manter

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Device dependent APCs.

Please reconsider the approach for reimbursement of expensive supplies with "C codes". If a drug that costs more than $50 is paid, a neurostimulator that costs over $5000 should be paid separately for logical consistency. Many implants, too, should be tracked and hospitals incur great expense. Especially expensive prosthetic implants , not requiring a hospital DME provider number, should be considered for separate payment.

Submitter : Mr. Ben Marion **Date:** 09/16/2005

Organization : Turning Point Hospital

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-609-Attach-1.DOC

Attachment #609

September 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS- CMS-1501-P

Turning Point Hospital is a hospital and psychiatric provider in the State of Georgia. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of $241.57 cannot be justified with these expenses.

2. CMS identified the Median cost of group therapy at $82.31. Our program offers 4 services per day at a minimum. This summarizes to a median cost of $329.24. A per diem of $241.57 cannot be justified with these expenses.

Attachment #609

3. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two-year periods.

4. Based on the above issues, Turning Point Hospital asks that CMS leave the per diem unchanged from the CY 2005 rate of $281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 789 admissions so far in CY 2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Ben Marion, CEO

BM/ds

Submitter : Mrs. Beth Shiring
Organization : UPMC Cancer Centers
Category : Hospital
Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-610-Attach-1.DOC

September 16, 2005

The Honorable Mark A. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

UPMC Cancer Centers welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule CMS-1501-P, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates."

UPMC Cancer Centers encompasses 180 cancer specialists at approximately 40 hospital-based and office-based locations throughout 12 counties in western Pennsylvania and serves a population of more than 6 million. Treating approximately 30,000 new patients per year, UPMC Cancer Centers is one of the largest cancer care networks in the nation. Our vast network represents the full spectrum of cancer care delivery including: physicians operating sole practices in rural areas; free-standing medical and radiation oncology facilities in rural and suburban areas; and a large group of academic physicians providing hospital-based outpatient care at the flagship Hillman Cancer Center in Pittsburgh.

Since our region has one of the highest concentrations of individuals age 65 and over, the age group most at risk of being diagnosed with cancer, we rely heavily on CMS to provide fair and adequate reimbursement for us to care for these patients. We commend CMS for its increased research and analysis into the costs of providing cancer care; however, we do have some concerns regarding the proposed rule that we outline below.

Proposed Payment for Drugs and Biologicals – Non Pass-Throughs

1. We agree with CMS' recommendation to continue to exempt oral and 5HT3 injectible anti-emetic products from packaging. Due to the debilitating side effects of chemotherapy treatments, our patients respond positively to anti-emetic therapy. Continuing to have access to these drugs reduces additional expenses that may be incurred due to complications from nausea induced dehydration and fatigue.

2. The "Packaging Threshold" (<$50) expires in December 06. The methodology for calculating cost of drugs needs to be reviewed. As of January 06 CMS will have a complete year of ASP data. Would it be appropriate to utilize the ASP as the parameter for the packaging threshold?

3. We support the intent of implementing ASP as an equitable basis for drug reimbursement; however, there are several problems with the current calculation. Some issues include:
    - ASP is based on the price that manufacturers charge to distributors, including any prompt pay discounts. These prices and discounts often are not passed along to providers but are included in the calculation of ASP.
    - ASP is based on sales to all entities, including group purchasing organizations and large hospital systems on one end of the spectrum and one-physician oncology practices on the other. It means that many hospitals, particularly the smaller ones without purchasing power, will purchase drugs above ASP.
    - We understand that there currently is a two-quarter lag in the calculation of ASP, meaning that reimbursement is based on prices that are six-months old. Since manufacturers typically raise prices two to three times per year, there is potential for hospitals to suffer losses each time they administer drugs. Even as a large volume buyer,

UPMC currently pays greater than ASP for many of our most highly utilized drugs and, in some cases, pay greater than ASP + 6%.

ASP+6% would have a negative impact of approximately 7-12% to our hospital-based locations drug revenue.

4. We commend CMS for proposing to add an additional 2% to ASP+6% for the separately payable drugs. This reduces the loss to our net revenue to a 5-10% reduction over CY05. However, we do not feel that 2% is adequate the cover the substantial costs associated with the handling and storage of toxic chemotherapy agents. We believe that further studies and additional guidance are needed to determine what is sufficient reimbursement for drug handling oncology setting.

5. CMS is considering establishing three C-codes, which are based upon the administration of each separately payable drug or biological, i.e. oral, Injections/IV Solutions, and Specialty/Cytotoxic Agents. This is a means for CMS to collect the costs associated with the pharmacy handling expenses. We are pleased that CMS is considering the collection of additional data; however, implementing these new codes does pose an operational burden the hospital billing staff. We ask that you consider a payment for collection of this data that is similar to the payment for the data collected during the Quality Measurement Demonstration Project that was implemented in physicians' offices in CY2005.

Drug Administration

CMS is considering converting the drug administration codes that were implemented on January 1, 2005 to G-codes, which are presently used in the physician office setting. We agree with the approach of using the G-codes as a basis for reimbursement. We believe the new codes will help CMS collect the data it needs to set more appropriate payment rates in the future. However, we urge CMS to provide adequate reimbursement for hospitals' costs of providing drug therapies, particularly for the large number of our patients who receive multiple infusions in a single visit or whose infusions take more than one hour to administer.

CMS proposes to map the new drug administration codes to existing APCs and to package payment for all codes that describe additional hours, subsequent infusions, or concurrent infusions into the code for the initial service. This proposal, combined with the CPT's instructions to report only one "initial" service code when administering multiple infusions or injections, means that hospitals will be paid only for the first hour of the first infusion service provided. All other services provided on the same day, including administration of other drugs or hydration, would not be reimbursed under the OPPS, although the same services would be paid when provided in a physician's office. If adopted for use under OPPS, the new coding guidelines would lead to reduced payments that would be inconsistent with existing and proposed OPPS payment policy.

We ask CMS to issue instructions to hospitals and fiscal intermediaries to clarify that unlike in a physician office, more than one "initial" code may be used for reporting drug administration services in the hospital outpatient setting. Additionally, we urge the agency to make separate payment for additional hours of infusion services.

Quality Measurement Demonstration Project

In 2005, CMS created a nationwide demonstration program open to all physician offices to measure and improve the quality of care provided to Medicare patients receiving chemotherapy. We are very supportive of CMS' effort to focus attention on quality of life issues for patients with cancer. Certainly, patients undergoing chemotherapy treatment face serious and unique issues, including problems associated with the powerful drugs they receive to fight their disease. Many of these drugs, like Cisplatin, Adriamycin, Cyclophosphamide, to name a few, are very effective in combating cancer. At the same time, these drugs have significant side effects causing patients to experience nausea, vomiting, and fatigue. As caregivers,

we must assess these symptoms continually because they have a dramatic effect on the comfort and, ultimately, the care patients receive.

This demonstration project was not only a useful data collection tool, but it helped ease the transition to ASP-based reimbursement and, therefore, access to chemotherapy by providing physicians with a fee for supplying this data to CMS. We ask that this demonstration project, or a similar project, be extended to hospitals in CY2006

UPMC Cancer Centers would like to thank you for the opportunity to offer our formal comments for your consideration. As always, we are committed to serving the senior citizen population through the Medicare program. We stand ready to work with you to improve that program so that seniors can continue to access the highest quality care.

Sincerely,

Beth Wild Shiring
Chief Operating Officer
UPMC Cancer Centers

Submitter : Harvey L. Neiman, M.D., FACR **Date:** 09/16/2005

Organization : American College of Radiology

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

9/16/05 American College of Radiology Letter to Hon. Mark B. McClellan, M.D.; re Proton Beam Therapy

CMS-1501-P-611-Attach-1.DOC

ACR™
AMERICAN COLLEGE OF RADIOLOGY

September 16, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, writes to provide comments on the "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" published in the Federal Register on July 25, 2005 as a proposed rule with the comment period ending on September 16, 2005.

Our comments will address multiple diagnostic imaging procedures, proposed changes to packaged services, proposed use of single and multiple procedure claims, brachytherapy proposed payment policies, proton beam therapy, stereotactic radiosurgery, contrast- enhanced imaging procedures, computerized reconstruction, drug handling costs, device-dependent APCs, and magnetoencephalography (MEG).

Multiple Diagnostic Imaging Procedures

In this rule, CMS proposes to implement the MedPAC recommendation to "reduce the technical component payment for multiple imaging services performed on contiguous body parts." Specifically, CMS proposes to make full payment for the procedure with the highest APC payment rate and to make a 50% reduction in the OPPS payments for some second and subsequent imaging procedures performed in the same session.

The ACR agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. However,

the ACR has serious concerns that CMS has used external rather than internal data and methodology as the basis for this proposal. In using the Medicare Physician Fee Schedule (MPFS) methodology and data, rather than that of the HOPPS/APC process, CMS has ignored the fact that the cost efficiencies of performing multiple imaging procedures in the same session are already captured and accounted for in hospitals' annual cost reports to CMS and therefore already factored into the APC payment calculation. Therefore, the ACR recommends that CMS abandon the MPFS methodology and instead use data and methodology internal to the HOPPS/APC process in this analysis.

The HOPPS/APC process requires each hospital cost center to annually submit its aggregate charges and costs for the year to CMS. From this data, a cost/charge ratio is determined for each cost center. This cost/charge ratio is applied to charges for specific procedures to determine true costs and those costs are summed nationally to derive a median upon which the APC value is based. The ACR and its consultants believe there is ample evidence to indicate that the cost efficiencies in the technical component, which occurs when some imaging procedures are performed in the same session, is already accounted for when a hospital cost center submits its annual cost data.

Since the HOPPS/APC methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in this proposed rule, would contradict this methodology and systematically disadvantage hospitals relative to other imaging facilities. It would also result in an unintended, inappropriate and severe financial penalty to hospitals, making it difficult for them to upgrade equipment, hire necessary staff and provide the same hours of outpatient imaging operation, thus decreasing access of necessary care to Medicare beneficiaries.

- The ACR therefore supports the APC Advisory Panel's recommendation to delay this proposal for one year because further study is necessary; and, to consult with the ACR in this process.

Proposed Changes to Packaged Services

For CY2006, CMS is proposing to accept the APC Panel recommendation that CPT code 76937 (Ultrasound guidance for vascular access) remain packaged into the vascular access procedure codes. CMS is concerned that there may be unnecessary overuse of this procedure if it is separately payable. However, CPT has set specific coding and documentation guidelines of when this service should be billed. In addition, CMS believes that the service would always be provided with another separately payable procedure, so its costs would be appropriately bundled with the definitive vascular access service. However, it is the more difficult line placements that are referred to radiology that require image guidance. The ACR is concerned that these services and their costs will not be properly allocated to the radiology cost centers.

Therefore, the ACR disagrees with the APC Panel recommendation that CPT code 76937 remain packaged. Instead, we ask that CMS allow for separate payment.

Based on the original Institute of Medicine's report, "To Err Is Human: Building a Safer Health System," a recommendation was made by the Stanford Group to increase ultrasound guidance during CV line placement to decrease patient morbidity. It would seem that packaging will discourage the increased use in guidance for those difficult cases as it only adds non-reimbursable cost to the procedures.

In addition, the Agency for Healthcare Research and Quality (AHRQ) deemed the use of ultrasound to guide vascular access to be one of eleven most highly rated clinical practices to improve patient safety.[1] Also, it has been documented that 25% of injuries related to central vascular catheters could have been prevented with the use of ultrasound.[2] However, lack of payment for investment in equipment is cited in the AHRQ report to be a hurdle to adoption of this patient safety measure. Furthermore, lack of separate payment suppresses hospital cost reporting on claims. Although CMS allows for reporting of packaged services, because there is no payment on those packaged services, hospitals often do not report them. As a result, it is unlikely that the payment rates of the vascular access procedures reflect the added costs associated with providing ultrasound guidance.

- To ensure that Medicare beneficiaries have access to safe, high quality care, the ACR recommends that the Status Indicator assigned to CPT code +76937 be changed to an "S" allowing for separate payment of this service when provided in the hospital outpatient setting and that CPT code +76937 be assigned to APC 0268 - Ultrasound Guidance Procedures.

Proposed Use of Single and Multiple Procedure Claims

For CY 2006, CMS is proposing to continue to use single procedure claims to set the medians on which the APC relative payment weights would be based. CMS agrees that, optimally, it is desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those with multiple procedures. CMS is also proposing to continue using date of service matching as a tool for creation of "pseudo" single claims and to continue the use of a bypass list to create "pseudo" single claims.

- The ACR has continuously supported Medicare's policy to utilize as much hospital claims data as possible in order to calculate the APC weights. The ACR encourages CMS to continue to search for better ways to use and incorporate multiple-procedure claims data into the calculation of the weights for APCs. This is critical in the areas of interventional radiology and radiation oncology where submission of multiple-procedure claims is the norm rather than the exception. The ACR would also like to ensure that current APCs for codes on the "bypass" list are not devalued by lack of good data in order to provide single claims for others.

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[1] AHRQ Evidence Report/Technology Assessment, No. 43 Making Health Care Safer: A Critical Analysis of Patient Safety Practices; 2001

[2] Anesthesiology 2004;100:1411-8. Injuries and Liability Related to Central Vascular Catheters. A Closed Claims Analysis.

Brachytherapy

All radiation oncology procedure codes (CPT codes 77xxx) have proposed increases in 2006 under HOPPS except brachytherapy codes in APCs 312, 313 and 651 which have proposed reductions (see Table 1).

The ACR believes that the proposed brachytherapy reductions are based on several factors, including: inaccurate hospital coding of brachytherapy source device "C" codes; elimination of multiple-procedure claims used to determine relative weights; and utilization of "incorrectly" coded brachytherapy claims to determine payment rates.

Table 1. Comparison of 2005 vs. Proposed 2006 HOPPS Payment Rates for Brachytherapy APCs

APC	CPT Codes	2005 Payment	2006 Proposed Payment	Percentage Change from 2005 to 2006
312 Radioelement Applications	77761, 77762, 77763, 77776, 77777	$317.87	$296.90	-6.6%
313 Brachytherapy	77781, 77782, 77783, 77784, 77779	$790.75	$763.48	-3.4%
651 Complex Interstitial Radiation Source Application	77778	$1,248.93	$720.71	-42.3%

- The ACR recommends the following: 1) use only "correctly coded" claims for brachytherapy APCs 312, 313 and 651; and 2) require mandatory hospital coding of appropriate brachytherapy source "C" codes for brachytherapy procedure APCs 312, 313 and 651.

Proposal to Move CPT 57155 from APC 193 to APC 192

CMS proposes to move CPT 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from APC 193 *Level V Female Reproductive Procedures* to APC 192 *Level IV Female Reproductive Procedures*. The current payment for CPT 57155 is $758.17 and decreases by 66.4% in 2006 with assignment in APC 192 with a 2006 proposed payment of $255.66. We note that some CPT codes were moved to different APCs without a discussion in the preamble providing the rationale for the changes. For example, there was no discussion in the proposed rule regarding the proposed assignment of CPT 57155 to APC 192 and we are concerned that a reduction of 66% could have a negative impact on Medicare beneficiaries' access to this important treatment for vaginal and/or uterine cancer.

- The ACR recommends that CMS maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures*. Further, we request that all changes to APC assignments be discussed in the preamble for future proposed and final rulemaking.

Proton Beam Therapy

CMS is proposing to move CPT codes 77523 and 77525 from New Technology APC 1510 ($850 for the CY 2005) to clinical APC 0667 (Level II Proton Beam Radiation Therapy) based on a median cost of $934.46 for CY 2006.

- The ACR agrees with this CMS proposal.

Stereotactic Radiosurgery

CMS is seeking public comment on the clinical, administrative, or other concerns that could arise if CMS were to bundle Cobalt 60-based Stereotactic Radiosurgery (SRS) planning services, currently reported using HCPCS code G0242 and proposed for CY 2006 to be billed using the appropriate CPT codes for planning services, into the Cobalt 60-based SRS treatment service, currently reported under the OPPS using HCPCS code G0243.

- The ACR recommends the elimination of HCPCS codes G0242 (Cobalt 60-based planning) and G0338 (linac-based planning) and instead utilize existing CPT codes as determined by the process of care. SRS treatment planning is already well described by CPT codes (77295, 3D simulation or 77301, IMRT planning) and other simulation and physics codes (77300, 77370 and 77315) are currently used by physicians for their portion of the procedure.

Contrast-Enhanced Imaging Procedures

The ACR thanks CMS for its proposal to pay separately for low osmolar contrast material and most MR contrast agents. We are concerned, however, that the separate payment will not adequately compensate for the reduced payment which CMS proposes for APC 283, *CT with Contrast Material, and* APC 333, *CT* and *CT Angiography without followed by with Contrast.*

- The ACR does not understand why CMS is proposing to reduce payments for APCs 283 and 333 to a level that results in an overall net loss for contrast-enhanced CT studies. The ACR recommends that CMS allow the cost data to naturally adjust the CT payment rates to account for LOCM being paid separately similarly to how this method was used when CMS ruled that all LOCM was packaged.

Computerized Reconstruction

The ACR notes, with concern, a proposed reduction in payment for APC 417, *Computerized Reconstruction* of $25. It was neither discussed in the preamble nor obvious in the 2006 data of why this decrease has occurred. Considering the possibility that computerized reconstruction may undergo significant changes in its coding structure which may result in recognition of the true complexity of these procedures and a subsequent marked reduction in their volume,

- The ACR recommends a one year delay in the implementation of the proposed reduction for APC 417 in order that the effect of changes in this technology be better reflected in its APC payment.

MedPAC Report on APC Payment Rate Adjustment of Specified Covered Outpatient Drugs

CMS proposes to pay for separately payable radiopharmaceutical agents based on their charges in the claims submitted by hospitals converted to costs. MedPAC found that the handling costs associated with radiopharmaceuticals were especially difficult to study given the variety of hospital outpatient settings in which these agents are used, the many different clinical uses for them, and significant differences in the agents themselves and in the methods for preparing them. As a result, handling costs for radiopharmaceuticals were found to vary a great deal due to differences in such factors as site of preparation, personnel time, shielding, transportation, equipment, waste disposal, and regulatory compliance requirements. However, as MedPAC also found that handling costs for drugs, biologicals, and radiopharmaceuticals were built into hospitals' charges for the products themselves. CMS believes that the charges from hospital claims converted to costs are representative of hospital acquisition costs for these agents, as well as their overhead costs. CMS is not proposing to create separate handling categories for radiopharmaceutical agents for CY 2006. However, CMS is proposing to collect ASP information for radiopharmaceuticals in CY 2006. CMS is seeking comments on appropriate categories for potentially capturing radiopharmaceutical handling costs.

- The ACR adheres to the APC Advisory Panel's recommendation that CMS delay for one year implementation of the proposed codes for drug handling cost categories so that further data and alternative solutions for making payments to hospitals for pharmacy overhead costs can be collected, analyzed by CMS, and presented to the Panel at the next meeting. The ACR would also like to be involved in this process.

Device-Dependent APCs

The ACR is concerned that CMS did not continue its policy of stabilizing all device-related APC rates by protecting against significant cuts to APCs. For the last several years, CMS established a "dampening" adjustment to virtually all APCs (except "New Technology" APCs). These adjustments were created to limit the impact of payment reductions from year to year.

In the 2006 proposed rule, CMS acknowledged that a payment reduction of more than 15% from the 2005 HOPPS payment rate might be problematic for hospitals that provide these services.

To address the lack of C-code data and the significant reductions for several APCs, CMS is proposing to adjust the median costs for the "device-dependent" APCs in Table 15 – "Proposed Median Cost Adjustments For Device-Dependent APCs For CY 2006" to 1) the higher of the 2006 unadjusted median or; 2) 85% of the adjusted median on which payment was based for 2005 HOPPS. The "device-dependent" adjustment factor proposed for 2006 was not applied to APC 651 for Complex Interstitial Brachytherapy.

- The ACR recommends that CMS apply the dampening adjustment to all device-related APCs, including APC 651, and limit the reduction in payment from 2005 to 2006 rates.

Other New Technology Services

CMS proposes to set magnetoencephalography (MEG) APC levels at $674 for all CPTs in FY 2006 decreasing from FY 2005 $5,250 (CPT 95965 - MEG, recording and analysis; spontaneous brain activity; $950 (CPT 95966 - Evoked magnetic fields, single modality); and $1,450 (CPT 95967 - Evoked magnetic fields, each additional modality).

- The ACR believes that the current values of reimbursement for MEG are at appropriate levels to reflect the actual costs. Similar to proton therapy, there are only a limited number of facilities that perform MEG. CMS' decision to change this payment rate for 2006 was based on a low volume of data and a wide range of charges. In addition, there does not appear to be any cost data for code 95967 possibly skewing the low recommended payment rate for 2006. Therefore, the ACR recommends delaying this proposal for one year in order for CMS to acquire additional data and reanalyze.

Conclusion

Thank you for the opportunity to comment on this proposed rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Carisia Switala at the ACR. Carisia may be reached at 1-800-227-5463 ext. 4587 or via email at CSwitala@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

cc: Herb Kuhn, CMS
Ken Simon, MD, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
James Rawson, MD, FACR, Chair, ACR Economics Committee on HOPPS/APC
Pamela J. Kassing, ACR
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Submitter : Mr. John Pavlidis **Date:** 09/16/2005

Organization : R2 Technology, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-612-Attach-1.PDF

#612

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September 16, 2005

BY ELECTRONIC FILING

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates) – New Technology APCs

Dear Administrator McClellan:

R2 Technology, Inc. (R2) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 25, 2005 (the "Proposed Rule").[1] R2 Technology, Inc., headquartered in Sunnyvale, CA, is a recognized leader in the development and commercialization of computer aided detection (CAD), an innovative technology that assists physicians in the earlier detection of breast cancer, actionable lung nodules and other lung abnormalities. As a medical software company, R2 Technology is developing CAD systems for a variety of imaging modalities and disease states.

We are keenly aware that patients can benefit from our technologies only if hospitals are appropriately reimbursed for them. The OPPS New Technology ambulatory payment classifications (APCs) help to ensure that hospitals are able

[1] 70 Fed. Reg. 42673 (July 25, 2005).

to provide advanced treatments and diagnostic services during the first few years the products are marketed, while also allowing CMS to collect the claims data necessary to make a permanent APC assignment. However, if new technologies are not assigned to the APCs in a timely manner, patient access to these products may suffer. Any delay also will affect CMS' ability to set adequate permanent reimbursement rates for these technologies.

R2 is greatly concerned about CMS' proposal to require applicants for New Technology APCs to first submit an application for a new Current Procedural Terminology (CPT®) code.[2] We believe this requirement adds unnecessary complexity to the application process and will delay beneficiary access to innovative technologies. The CPT® application process requires months of preparation, research, and consultations with specialty societies and CPT® Editorial Board staff. Once an applicant has gathered all the required information and prepared clinical vignettes, it must wait for the relevant CPT® committees to review this information. This process can be particularly time-consuming when applying for a Category I code, because of various requirements specific to the CPT® process. Under CMS' proposal, a technology could not be assigned to a New Technology APC until after all of these standards are met. Alternatively, if an applicant fails to meet these standards and does not have adequate support, the technology likely will be granted a Category III code. Although CMS proposes to accept either a Category I or Category III application, manufacturers are reluctant to seek a Category III code because these codes are frequently denied coverage by Medicare contractors and private payors.

R2 respectfully disagrees with CMS' conclusion that this requirement "will encourage timely review by the wider medical community as CMS is reviewing the service for possible new coding and assignment to a New Technology APC under the OPPS."[3] Instead, we believe the proposed requirement will discourage manufacturers from seeking New Technology APC assignments, preventing many advanced technologies from receiving appropriate OPPS payments. If faced with the risk of receiving a Category III code, manufacturers likely will postpone applying for both a CPT® code an New Technology APC assignment until all of the data necessary for a Category I code have been gathered. In the meantime, new technologies would be billed using miscellaneous codes, which limit CMS' ability to gather the data needed to set appropriate payment rates. Because hospitals would not receive adequate reimbursement for these products, they would choose not to offer them, limiting beneficiaries' choices of treatment and diagnostic options.

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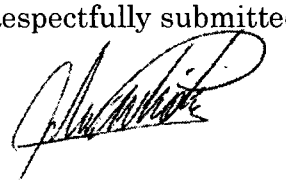
2 70 Fed. Reg. at 42707.
3 Id. at 42707.

R2 thanks CMS for this opportunity to comment on the Proposed Rule. Please do not hesitate to contact me or Denise Gottfried, VP Regulatory, Quality and Clinical Affairs at (408) 481-5646 or at dgottfried@r2tech.com if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



John D. Pavlidis
President and CEO